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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,892	12/15/2000	Mark G. Obukowicz	3374 (PHA 4140)	2003

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SENNIGER POWERS LEAVITT AND ROEDEL
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ST LOUIS, MO 63102

EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1651	6

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/737,892	OBUKOWICZ ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of *Vitex agnus-castus* in Paper No. 5 is acknowledged. The traversal is on the ground(s) that any search of the prior art and examination involving such an extract from one edible plant species, therefore, will necessarily co-extend with the search and examination of edible plants belonging to other species. This is not found persuasive because this is not a restriction requirement but an election of species. If applicant wants to admit on the record that the different species are obvious variants over one another then the examiner may consider withdrawing the election of species, but since this is an election of species and since the examiner has found applicant's elected species in the prior art, the traverse is moot. Further, it is clear in the specification that applicant is claiming an extremely large group of plants that the claimed extract can be extracted from. It is an undue burden on the examiner to search such a broad range of plants and these plants are not related to one another, thus they are drawn to materially distinct plant species. Also, the applicant is reminded of the fact that the search for these plants while being extensive is not co-extensive since there is the extensive literature search involved in searching biotechnology cases.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Further, the oath does not recognize the parent application, 09/272,363.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-79, 81, 85-93 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 248215 (abstract).

EP teaches an alcohol extract of *Vitex agnus-castus* which can be used to treat diseases caused or influenced by dopamine deficiency. The extract when administered to a patient will inherently produce the claimed results.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 248215 taken with Hawley's Condensed Chemical Dictionary.

The teachings of EP are above. EP does not teach to use the specific solvent dichloromethane (methylene chloride) for the extraction of the elected plant, that the plant and the organic solvent are mixed at a temperature between about 25 ^{0}C and the boiling point of the solvent for at least one minute, and that the separating of the solvent from the organic extract is done by evaporating the solvent.

Hawley's teaches that methylene chloride is known to be used for solvent extractions, see page 736.

It would have been obvious for one of ordinary skill in the art to use methylene chloride instead of an alcohol in the method of EP since Hawley's makes it clear that methylene chloride is well known to be used for solvent extraction. Since plant extracts can be extracted with many different types of solvents and alcohols, it is merely the choice of the artisan in an effort to optimize the results to use methylene chloride to extract the claimed plant to be used in the claimed process. It is simply a matter of routine experimentation and optimization to use methylene chloride in the claimed process since Hawley's makes it clear that methylene chloride is so well known to be used for solvent extraction.

To mix the elected plant and the organic solvent at a temperature between about 25 ^{0}C and the boiling point of the solvent for at least one minute is simply the choice of the artisan in an effort to optimize the results. Further, the range of 25 ^{0} C and the boiling point is such a large range, that one of ordinary skill in the art could easily contemplate such a large range and to do it for one minute is also obvious since one minute is long enough to yield the extraction desired from the plant and is clearly within the purview of the skilled artisan since it is a well known time period to do such an extraction at. To separate the solvent from the organic extract by evaporating the solvent is obvious since evaporation is a well known technique for driving off solvents, further it is very easily and effectively done.

The extract when administered to a patient will inherently produce the claimed results.

Claims 1-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000236835 in view of EP 248215 and Hawley's Condensed Chemical Dictionary.

JP teaches that *Vitex agnus-castus* is used in a food for the prevention of cancer. JP does not teach to use the specific solvent dichloromethane (methylene chloride) for the extraction of the elected plant, that the plant and the organic solvent are mixed at a temperature between about 25 ^{0}C and the boiling point of the solvent for at least one minute, and that the separating of the solvent from the organic extract is done by evaporating the solvent.

The teachings of EP are above.

Hawley's teaches that methylene chloride is known to be used for solvent extractions, see page 736.

It would have been obvious for one of ordinary skill in the art to extract the *Vitex agnus-castus* in JP since EP makes it clear that such a plant can be readily extracted with an alcohol and to use methylene chloride instead of an alcohol would have been obvious since Hawley's makes it clear that methylene chloride is well known to be used for solvent extraction. Since plant extracts can be extracted with many different types of solvents and alcohols, it is merely the choice of the artisan in an effort to optimize the results to use methylene chloride to extract the claimed plant to be used in the claimed process. It is simply a matter of routine experimentation and optimization to use methylene chloride in the claimed process since Hawley's makes it clear that methylene chloride is so well known to be used for solvent extraction.

To mix the elected plant and the organic solvent at a temperature between about 25 ^{0}C and the boiling point of the solvent for at least one minute is simply the choice of the artisan in an effort to optimize the results. Further, the range of 25 ^{0} C and the boiling point is such a large range, that one of ordinary skill in the art could easily contemplate such a large range and to do it for one minute is also obvious since one minute is long enough to yield the extraction desired from the plant and is clearly within the purview of the skilled artisan since it is a well known time period to do such an extraction at. To separate the solvent from the organic extract by evaporating the solvent is obvious since evaporation is a well known technique for driving off solvents, further it is very easily and effectively done.

The extract when administered to a patient will inherently produce the claimed results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM
January 11, 2002

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1657